AUG 1 1 2000

K002114

PERUSAHAAN PELINDUNG GETAH (M) SDN BHD
(Company No. 169997-P)
Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat,
Senawang Industrial Estate, 70450 Seremban,
Negeri Sembilan Darul Khusus, Malaysia.
Tel: 606-6772781 Fax: 606-6772780

Amendment # 1

510(K) SUMMARY

Applicant:	PERUSAHAAN PELINDUNG GETAH (M) SDN BHD
Address	Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan, Malaysia.
Phone No.	60-6-6772781 Fax No. 60-6-6772780
Contact Person	Peter Yew Nieng Choon
Date of Summary	3rd August 2000 (original date: 7th July 2000)

Device Information

Trade Name	RUBBERCARE POLYMER-COATED POWDER-FREE LATEX EXAMINATION GLOVES GUARDIAN POLYMER-COATED POWDER-FREE LATEX EXAMINATION GLOVES
Common Name	Polymer-coated Powder-free Latex Exam Gloves
Classification Name	Patient Examination Gloves

Claim of Equivalence

The device is a class I latex patient examination gloves 80LYY which is made low powder by a process of polymer-coating and meets all the requirements of ASTM standard D 3578-99.

Device Description

It is the powder-free variation of the class I latex patient examination gloves made by on-line polymer-coating and followed by off-line polymer-coating. The process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder. It is particularly suitable to users who prefer a powder-free work environment or who may be sensitive or allergic to the powdered version of the same gloves.

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Intended Use of Device

The device is intended as a protective device to be worn on the hands of healthcare or similar personnel to prevent cross-contamination between the wearer and the person being examined.

Technological Characteristics

Following is a table showing the measured parameters of the gloves (e.g. lengths, thickness, widths, physical properties, protein contents, etc) as compared to ASTM. Also data that meets FDA biocompatibility, pinhole, powder-free and any other requirements, and any other parameter on which we want to make a labeling claim.

Parameter	ASTM Specifications	Measured Values
Length, mm	230 min.	240 – 245
Thickness (palm), mm	0.08 min.	0.14 – 0.16
Thickness (finger), mm	0.08 min.	0.16 – 0.20
Width (size M), mm	95 ± 10	94 – 98
Tensile Strength, Before Aging, Mpa	14 min.	24 – 32
Tensile Strength, After Aging, Mpa	14 min.	20 – 28
Ultimate Elongation, Before Aging, %	700 min.	800 – 900
Ultimate Elongation, After Aging, %	500 min.	700 – 800
Water Extractable Protein, µg/gram	n.a.	100 and below
Water Leak Test, Before Aging, AQL	2.5	1.5 and below
Water Leak Test, After Aging, AQL	4.0	2.5 and below
Residual Powder (size M), mg/glove	n.a.	2 and below
Skin Irritation Test	n.a	Passed*
Dermal Sensitization Test	n.a	Passed*

* Please refers to ***attachment N (RC04)***

Conclusions

Based on the test data given above, we certify that our gloves:

a. meet or exceed the ASTM standard D 3578-99
b. meet the FDA pinhole requirements; and
c. meet our labeling claim on protein content.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2000

Mr. Peter Yew Nieng Choon
Managing Director
Perusahaan Pelindung Getah (M) SDN BHD
Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat
Senawang Industrial Estates, 70450 Seremban,
Negeri Sembilan Darul Khusus
MALAYSIA

Re: K002114
Trade Name: Rubbercare Guardian Polymer-Coated Powder-Free Latex Examination Gloves: contains 100 micrograms or less of total water extractable protein per gram
Regulatory Class: I
Product Code: LYY
Dated: July 10, 2000
Received: July 12, 2000

Dear Mr. Choon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Amendment # 1

INDICATION FOR USE

Applicant: PERUSAHAAN PELINDUNG GETAH (M) SDN BHD

510(k) No. K002114

Device Name: Rubbercare, Guardian
Polymer-coated Powder-free Latex Examination Gloves
Contains 100 mcgm or less of total water extractable Protein per gram.

Indications for Use

The device is intended as a protective device to be worn on the hands of healthcare or similar personnel to prevent cross-contamination between the wearer and the person being examined.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002114